REMARKS

Claims 2-12 and 14-17 are pending in this application. Claims 2-12 and 14-17 are rejected. Claims 13, and 18-38 are withdrawn from consideration as being drawn to a non-elected invention. By the present amendment, claims 2, 13, and 18-38 are cancelled without prejudice or disclaimer, and claims 3-12 and 14-17 are amended. As they are fully supported by the instant application as filed, the amendments add no new matter.

Specification

The Examiner noted the use of the trademark Profilactis™ in the description. The Examiner consequently request capitalizing said trademark wherever it appears and be accompanied by the generic terminology. In this regard, the Applicants submit that the MPEP (608.01(v)), under title Examiner Note, states: "*Capitalize each letter of the word in the bracket or include a proper trademark symbol, such as ™ or ®.*" Consequently, it is believed that every trademarks recited in the description have been properly identified by the inclusion of the trademark symbol "™". Further, the trademark "Profilactis™" is a trademark owned by the Applicants. It is believed that the nature of such trademark is respected and that every effort has been made to prevent its use in any manner which might adversely affect its validity.

Claim Objections

The Applicants submit that claim 2 has been cancelled as requested by the Examiner.

Claim Rejections - 35 USC § 112

Claim 3 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner mentioned that the term "in association" in claim 3 is a relative term which renders the claim indefinite. In this regard, the Applicants respectfully submit that said objected-to term has been deleted from claim 3. Reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

Claims 2-8, 11, 12, 14 and 15 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that

the claims recite an "immunomodulator chemotherapeutic adjuvant" that can elicit an immune response, but it is not provided in the description the characteristics of said adjuvant that correlates to the functional aspect of being an "immunomodulator chemotherapeutic adjuvant" eliciting an immune response. In this regard, the Applicants wish to first point out that former claim 2 has been deleted. In addition, claim 3 has been amended in order to define that it is the claimed composition which elicit an immune response in the patient. Further, the claims now pending have been amended to recite an immunomodulator chemotherapeutic compound. In fact the term "adjuvant" was arbitrarily used, but its meaning (i.e. to be a compound) has always been clear from the disclosure. Such immunomodulator chemotherapeutic compound is known from the person skilled in the art, in light of the examples provided in the disclosure. Thus, it is believed unnecessary to define the immunomodulator chemotherapeutic compounds encompassed in terms of their structural or physical properties, since it is the composition and not the compound alone which is eliciting the immune response. Further, it is stated in the Manual of Patent Examining Procedure that:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the genus" (Manual of Patent Examining Procedure 2163.05).

It is thus believed that the present description discloses a sufficient and/or representative number of species. For example, at page 10 (third paragraph) of the description, the following immunomodulator chemotherapeutic compounds are recited: taxanes, Paclitaxel (Taxol™), cisplatine, doxorubicin, cyclophosphamide and 5-fluorouracil. In addition, Examples V and X-XII discloses *in vivo* results obtained with Paclitaxel, doxorubicine and cisplatine, as part of the composition taught in the present application. A person skilled in the art would know how to identify an immunomodulator chemotherapeutic compound that fall within the scope of the claims presently pending following the teaching found in the description. Thus, it is believed

unnecessary to further define the encompassed compounds in terms of their structural or physical properties, since the written description requirement for a claimed genus are believed to have been satisfied. The Applicant submits that a "representative number of species" have been adequately described by actual reduction to practice, as stated and require by the Examiner on page 5 of the pending Office Action. Reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

Claims 2-12 and 14-17 have been rejected under 35 U.S.C. 112, first paragraph, because the Examiner is of the opinion that the specification, while being enabling for an anti-cancer composition comprising an antigen in association with an effective amount of paclitaxel, wherein said antigen is inactivated tumor cells, it does not reasonably provide enablement for an anti-cancer vaccine composition comprising an antigen in association with an effective amount of any immunomodulator chemotherapeutic adjuvant. The Examiner is citing multiple references in order to establish that the present description is failing to provide any guidance to how the lack of efficacy which would be expected in light of the teaching found in the art is circumvent. More specifically, the Examiner points out that the specification does not provide any disclosure that the administration of the claimed polypeptides of antibodies would provide a therapeutic or prophylactic immune response against tumor *in situ*. In this regard, the Applicants submit that former claim 2 has been deleted and that claims 3-12 and 14-17 have been amended to be directed to an anti-cancer composition. Consequently, as acknowledged by the Examiner, it is believed that the present description is enabling for an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound, not only Paclitaxel (as other compounds have been exemplified), and a pharmaceutically acceptable carrier, said composition eliciting an immune response in a patient, and wherein said antigen is inactivated tumor cells. Further, the Examiner seems to restrict the scope of the present invention to a composition only comprising an antigen and Paclitaxel. In this regard, the Applicants reiterate that at page 10 (third paragraph) of the description, the following immunomodulator chemotherapeutic compounds are recited: taxanes, Paclitaxel (Taxol^{TM}), cisplatine, doxorubicin, cyclophosphamide and 5-fluorouracil. In addition, Examples V and X-XII discloses *in vivo* results obtained with Paclitaxel, doxorubicine and cisplatine, as part of the composition taught in the present application. Thus, a person skilled in the art would know how to identify compounds that fall within the scope of the claims presently pending following the teaching found in the

description and it is believed unnecessary to restrict the scope of the claims to a composition comprising Paclitaxel, and not potentially other immunomodulator chemotherapeutic compounds.

Further, the Applicants submit that it is stated in the Manual of Patent Examining Procedure (MPEP 2107.03, section IV) that:

> If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will ***be sufficient to establish therapeutic or pharmacological utility*** for a compound, composition or process.

Examples V and X-XII provides results in an animal model demonstrating the efficacy of the claimed composition. In view of the efficacy of the claimed anti-cancer composition to treat or immunized *in vivo* models following administration of the composition, there is credibility in asserting utility of the claimed composition to provide a therapeutic or prophylactic immune response against tumor *in situ*. In addition, Example V is believed to be a demonstration of the efficacy of the composition claimed in the present application to provide a therapeutic or prophylactic immune response against a tumor *in situ* in an animal model. In addition, Applicants respectfully remind the Examiner that:

> Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders (MPEP 2107.03, section IV).

Thus, the USPTO is not entitled to substitute itself to the FDA in order to evaluate the clinical relevance of the present invention. Since it is believed that all the requirements to ascertain the utility of the claimed composition have been fulfilled, and in view of the arguments presented hereinabove, reconsideration and withdrawal of Examiner's rejection are earnestly solicited.

Claim Rejections - 35 USC § 102

Claims 2-12 and 14-15 have been rejected under 35 U.S.C. 102(e) as being anticipated by

Hiserodt *et al.* (US Patent No. 6,277,368) (hereinafter "Hiserodt *et al.*) The Examiner mentioned that the reference of Hiserodt *et al.* teaches cellular vaccines and methods of using them in cancer immunotherapy, particularly humans. Further, the Examiner is also of the opinion that Example 7 of Hiserodt *et al.* discloses a combination method for treatment using IL4-secreting 4Cl 107 cells mixed with autologous tumor cells along with adjuvant chemotherapy with Cisplatin. In this regard, the Applicants submit that the reference of Hiserodt *et al.* is teaching the use of a vaccine in cancer immunotherapy. As mentioned in the abstract of Hiserodt *et al.*, the disclosed vaccines only comprise a source of tumor-associated antigen and a cytokine-secreting cell-line. However, the vaccines taught by Hiserodt *et al.* do not contain an effective amount of at least one immunomodulator chemotherapeutic compound. On the contrary, Hiserodt *et al.* teaches, as acknowledged by the Examiner, that the vaccines can be given following, preceding, in lieu or, or in combination with, other therapies. In particular, Example 7 in Hiserodt *et al.* describes the use of a vaccine in combination with chemotherapeutic agents such as cisplatin, which was administered intravenously. More precisely, as recited in Example 7 which the Examiner is referring to, nine days after the last injection of the vaccines disclosed in Hiserodt *et al.*, patient began weekly adjuvant chemotherapy. Thus, a person skilled in the art would acknowledge that Hiserodt *et al.* is not teaching a composition eliciting an immune response in a patient comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells, all in the same composition. Reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

Claims 2, 3, 5, 6, 11, 12, 14 and 15 are rejected under 35 U.S.C. 102(b), as being anticipated by Wang *et al.* (Cancer Immunol. Immunother. 1986) (hereinafter "Wang *et al.*") The Examiner mentioned that the reference of Wang *et al.* teaches a combination treatment of an anti-cancer agent (CL 259,763) and an inactivated L1210 leukemia vaccine given to mice challenged with P3888 murine leukemia. In this regard, the Applicants submit that the reference of Wang *et al.* is teaching the administration of CL 259,763 to animals by gavage (see page 8, second column, fourth paragraph of Wang *et al.*). Further, it is clearly indicated in Wang *et al.* (page 10, first column, third paragraph) that the mice were vaccinated with L1210 tumor cell and subsequently given test compound by gavage. Thus, Wang *et al.* is teaching a vaccine not containing an anti-cancer agent, which is administered concurrently with said anti-cancer agent.

On the contrary, the present application is teaching and claiming an anti-cancer composition eliciting an immune response in a patient comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells, all in the same composition. It is believed that the claims presently on file are novel in view of the teaching found in Wang *et al.* and reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

It is submitted therefore that the claims are in condition for allowance. Reconsideration of the Examiner's rejections are respectfully requested. Allowance of claims 3-12 and 14-17 at an early date is solicited.

In the event that there are any questions concerning this response, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

No additional fees are believed to be necessitated by this Amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 03-0172 for any underpayment or to credit any overpayment.

Respectfully submitted,

Date: December 21, 2007

By: /Pamela A. Docherty/
Pamela A. Docherty, Reg. No. 40,591
Telephone: (216) 622-8416